CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

STATE OF DELAWARE
DEPARTMENT OF STATE
DIVISION OF PROFESSIONAL REGULATION
BOARD OF PHARMACY

TELEPHONE: (302) 744-4500
FAX: (302) 739-2711
WEBSITE: DPR.DELAWARE.GOV

APPLICATION FOR PHARMACY-MANUFACTURER PERMIT
INSTRUCTION SHEET

When to File Application

This is the application for facilities that manufacture or package drugs, toilet preparations, dentifrices, or cosmetics in Delaware.

File this application for a Pharmacy-Manufacturer license when applying for an initial license OR re-applying when a previous Delaware license has lapsed and is no longer renewable. Since these licenses are not transferable, you must also file this application to report when a manufacturer already licensed in Delaware:

- Changes ownership (controlling interest), or
- Relocates.

A Pharmacy-Manufacturer permit terminates automatically when the controlling interest in the facility changes, the facility's legal existence ends, or the business ceases to operate (24 *Del. C*. §2540 (d)).

How to Apply

Please read and follow instructions carefully. Failure to follow instructions may delay your application.

☐ Submit completed, signed and notarized *Application for Pharmacy-Manufacturer Permit*.
- Applications that are incomplete, unsigned or not notarized will be rejected.

☐ Enclose non-refundable processing fee by check or money order made payable to the "State of Delaware."

☐ If the firm is registered with the Food and Drug Administration or Drug Enforcement Administration, enclose results of last GMP inspection.

Inspection Requirement

In addition to meeting the requirements above, the facility must be inspected before opening. A representative of the manufacturer must notify the Board office when the facility is ready for inspection. When the facility passes the final inspection, the Board office will issue the license.

Reporting a Manufacturer Name Change

If the facility's name changes, but ***there is no change in ownership nor in location***, it is not necessary to submit an *Application for Pharmacy-Manufacturer Permit*. Instead, submit:

☐ Letter notifying the Board of the change that includes the manufacturer's old name and new name, license number and effective date of the change.

☐ Duplicate license fee by check or money order made payable to the "State of Delaware."
- The duplicate license will show the new name, but the license number will not change.

Controlled Substances Registration

If the facility also manufactures controlled substances, a separate *Controlled Substances Application for Facilities* application is required.

A manufacturer must have a Delaware Pharmacy-Manufacturer permit, Delaware controlled substance registration and federal DEA permit before manufacturing controlled substances in Delaware.

For Board of Pharmacy Use Only
- ☐ **Verification**
- ☐ **Background**
- ☐ **Office Approval**
- ☐ **Inspection**

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TYPE OF APPLICATION

1. Select the items that describe the type of application:

   ☐ Initial Application –
   - ☐ This manufacturer has never held a Delaware Pharmacy-Manufacturer license.
   - ☐ This manufacturer previously held Pharmacy-Manufacturer license number **A5-** _____ that has lapsed and is no longer renewable.

   ☐ Application Due to Change of Ownership – Pharmacy-Manufacturer license number **A5-** _____

   ☐ Application Due to Relocation of Facility – Pharmacy-Manufacturer license number **A5-** _____

CONTACT AND LOCATION INFORMATION

2. Name of Business (as it should appear on license): _____

3. Enter all other trade or business names you use (or have used) such as "doing business as" or "formerly known as" names: _____ _____ _____

4. ***Location (Site of Manufacture)*** **Address**: _____
   Street (*No PO Boxes*)

   _____ _____ _____
   City State Zip

5. Phone: _____ Email: _____

6. ***Mailing*** **Address** (*if different from physical location*): _____

   _____ _____ _____
   City State Zip

7. Name of Contact Person: _____ ☐ Owner ☐ Manager ☐ Other

8. Phone (*if different from physical location*): _____ Email: _____

INFORMATION ABOUT OWNERSHIP

9. Form of Business (check one)

   ☐ Sole Proprietor or Individual with federal employer identification number – Go to Question 10
   ☐ Partnership – *Skip* to Question 11
   ☐ Corporation – *Skip* to Question 11

10. Enter the following information about the owner and then skip to Question 12.

    Full Name: _____ Social Security Number: _____

11. If a partnership, list ***all active partners***. If a corporation, list ***all principal officers***. (If you need more room, attach a separate sheet.)

FULL NAME	SOCIAL SECURITY NUMBER

12. Do you understand that the Board must be notified within ten days of a change of ownership? Yes ☐ No ☐

13. Federal Employer Identification Number: _____

LICENSURE HISTORY

14. Does the manufacturer hold any state or federal licenses, registrations, or permits authorizing the manufacture of drugs? Yes ☐ No ☐ **If yes, attach a list of license/registration/permit numbers and the jurisdiction that issued them.**

15. Is the firm registered with the Food and Drug Administration or Drug Enforcement Administration? Yes ☐ No ☐ **If yes, enter the following information and enclose results of last GMP inspection.**

    Registration Number: _____ Date of Last GMP Inspection: _____

SUPERVISION OF MANUFACTURING

16. Enter the names of supervisor(s): _____ _____ _____
    If you need more room, attach a separate sheet.

17. Is each supervisor listed qualified by scientific or technical training, education or experience to perform the duties of supervision that are necessary to protect public health, safety and welfare? Yes ☐ No ☐

DISCLOSURES

18. Have any of the owners, corporate officers or supervisors listed above ever been convicted of or entered a plea of guilty or *nolo contendere* (no contest) to any felony, misdemeanor or any other criminal offense, including any offense for which they have received a pardon, in any jurisdiction? Yes ☐ No ☐ **If yes, explain in detail on a separate sheet and arrange for the Board office to receive a state and federal criminal background check for all persons.**

19. Are any of the owners, corporate officers or supervisors listed above presently charged with committing a felony? Yes ☐ No ☐ **If yes, explain in detail on a separate sheet**

20. Have any of the owners, corporate officers or supervisors listed above ever applied for a manufacturer permit in any State and had the application denied? Yes ☐ No ☐ **If yes, explain in detail on a separate sheet.**

21. Has any of the owners, corporate officers or supervisors listed above ever been the subject of any disciplinary action (formal or informal) by any federal or state agency including, but not limited to, revocation or suspension of a license or registration or is any such action pending? Yes ☐ No ☐ **If yes, explain in detail on a separate sheet and enclose any relevant documents.**

PRODUCTS

22. List the products the facility will package or manufacture: _____
    _____
    _____
    _____

23. Will you manufacture controlled substances? Yes ☐ No ☐

A manufacturer must have a Delaware Pharmacy-Manufacturer permit, Delaware controlled substance registration and federal DEA permit before manufacturing controlled substances in Delaware.

When your application is complete, please allow 4-8 weeks to receive your license. A complete application is one that includes all required documentation and correct payment.

Applications that are not complete within six (6) months of filing may be considered abandoned and discarded.

AFFIDAVIT

I do hereby make application to the Board of Pharmacy for license or registration under the provisions of an Act to regulate the practice of Pharmacy in the State of Delaware and solemnly swear and affirm that the answers to the questions set forth in this application are true and correct.

Printed Name: _____ Title: _____

Signature: _____ Date: _____

State of _____ County of _____

Subscribed and sworn to before me this_____day of_____, 2_____

Witness my hand and seal hereunto attached.

Notary Signature:_____

SEAL

My Commission expires: _____

APPLICATIONS THAT ARE NOT SIGNED, NOT NOTARIZED, INCOMPLETE OR NOT ACCOMPANIED BY THE REQUIRED PROCESSING FEE WILL BE REJECTED.